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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,376

05/12/2006

Jerome S. Brody

BOSU-001-301

8226

75436

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07/09/2008

MORSE, BARNES-BROWN & PENDLETON, P.C.

ATTN: PATENT MANAGER

RESERVOIR PLACE

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WALTHAM, MA 02451

EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,376	<b>Applicant(s)</b> BRODY ET AL.	
	<b>Examiner</b> KATHERINE SALMON	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 13, 14, 17, 20-24, 26, 32-38, 45, 46 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) 17, 20-24, 26, 32-38, 45, 46 and 50-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 13-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election of Group I, Claims 1-5,7, and 13-14 in the reply filed on 4/07/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-5, 7, 13-14, 17, 20-24, 26, 32-38, 45-46, 50-53 are pending. Claims 17, 20-24, 26, 32-38, 45-46, 50-53 are withdrawn as being drawn to a nonelected invention.
3. An action on the merits for Claims 1-5, 7, and 13-14 is presented below.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-5, 7, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jalowsky et al. (US Patent 4800896 January 31, 1989) in view of Garcia-Closas (Cancer Epidemiology, Biomarkers and Prevention 2001 Vol 10 p. 687).

With regard to Claim 1, Jalowsky et al. teaches a collector probe (e.g. a scraping instrument) for collecting biological samples (abstract). Jalowsky et al. teaches the instrument has a proximal handle end (18), a distal collection end (4) and a joining portion between the two (10) (Figure 3). Jalowsky et al. teaches the joining portion is generally continuous to the width with the handle end on one side and the collection end on the other (Figure 3). Jalowsky et al. teaches that the collection end comprising a depressed end with a serrated edge (32) (Figure 3).

With regard to Claim 2, Jalowsky et al. teaches the collection end is spoon shaped (Figure 3).

With regard to Claim 3, Jalowsky et al. teaches that the device is comprised of plastic (column 2 lines 43-46).

With regard to Claim 4, Jalowsky et al. teaches the joining portion can be taking on or off (e.g. perforated) (column 7 lines 30-35).

With regard to Claim 5, Jalowsky et al. teaches the length of the device is about 10 cm (about 3 inches) (Column 6 lines 18).

However, Jalowsky et al. does not teach a storage vessel and a stabilizing solution.

Garcia-Closas teaches a kit which is mailed to collect buccal samples. With regard to Claims 1 and 13, Garcia-Closas et al. teaches that samples were taken from

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the patient and mailed in sealed plastic tubes (e.g. a storage vessel) (abstract and p. 688 2nd column last paragraph). Garcia-Closas teaches the addition of a stabilization solution to isolate RNA (p. 659 2nd column 2nd paragraph).

With regard to Claim 7, Garcia-Closas teaches a storage vessel to fit a collection device into (p. 688 2nd column last paragraph).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to modify the kit comprising a scraping instrument of Jalwayski et al. to further include a storage vessel and a stabilization solution as taught by Garcia-Closas with a reasonable expectation of success. The person of ordinary skill in the art at the time of filing would be motivated to use a storage vessel and a stabilization solution because Garcia-Closas teaches the ability to mail sample devices to patients and then process them in a laboratory (abstract). The ordinary artisan would want to perform this method in order to collect samples easily from the population.

### ***Conclusion***

7. No Claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/  
Examiner, Art Unit 1634

/Ram R. Shukla/  
Supervisory Patent Examiner, Art Unit 1634